**Food and Agriculture Organization of the United Nations**

**World Health Organization**

***JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES***
***Seventy-fifth meeting***

# Veterinary Drug Residues in Food

**Rome, 7 – 17 November 2011**

## LIST OF SUBSTANCES SCHEDULED FOR EVALUATION AND REQUEST FOR DATA

Issued 15 April 2011

Attached is the list of substances (Annex 1) scheduled for evaluation or re-evaluation at the Seventy-fifth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). This list has been prepared by the Joint FAO/WHO Secretariat of the Committee and is based on recommendations of the Codex Committee on Residues of Veterinary Drugs in Foods and previous provisional decisions of the Committee.

### *Submission of data*

Governments, interested organizations, producers of these chemicals, and individuals are invited to submit data relating to the compounds listed in Annex 1. The submitted data may be published or unpublished and should contain detailed reports of laboratory studies, including individual animal data. Reference should be made to related published studies, where applicable. Summaries in the form of monographs are helpful, but they are not in themselves sufficient for evaluation.

Unpublished confidential studies that are submitted will be safeguarded and will be used only for evaluation purposes by JECFA. Summaries of the studies will be published by FAO and WHO after the meetings in the form of specifications and toxicological monographs.

FAO and WHO have only limited data storage capacity. The submitted data can either be returned to submitters at their expense or destroyed after the evaluations have been completed. Please indicate the preferred procedure for data disposal at the time of submission. Key material can be stored up to five years and will then be destroyed. For substances that are being re-evaluated, the FAO and WHO Secretariats of JECFA encourage the sponsor to contact them before submission of data to determine whether documents and data reviewed at previous meetings of the Committee should be re-submitted.

The secretariats of JECFA at FAO and WHO encourage electronic submissions. Such data should be presented preferably using standard word processing or document formats, and should be submitted on CD-ROMs. To facilitate review, an effort should be made to provide a “Table of contents” on each CD-ROM using fully descriptive file names.

***Date for submission***

The submission of data on those compounds listed in Annex 1 is requested before

**15 June 2011**.

This deadline applies to all data to be submitted.

***Toxicological data***

Data relevant to the toxicological evaluation of the substances on the agenda, including:

1. pharmacokinetic, metabolic, and pharmacodynamic studies in experimental and food-producing animals, and in humans when available;
2. short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity and developmental toxicity studies in experimental animals and genotoxicity studies;
3. special studies designed to investigate specific effects, such as those on mechanisms of toxicity, hormonal effects, immune responses, or macromolecular binding;
4. for compounds with antimicrobial activity, studies designed to evaluate the possibility that residues of the compound might have an adverse effect on the microbial ecology of the human intestinal tract; and
5. studies providing relevant data on the use of and exposure to the drug by humans, including studies of effects observed after occupational exposure and epidemiological data following clinical use in humans

should be sent to:

International Programme on Chemical Safety
Attention: Dr. Angelika Tritscher
World Health Organization
Avenue Appia
1211 Geneva 27
Switzerland
Facsimile: (+41 (0)22) 791 4848
Telephone: (+41 (0)22) 791 3569
E-mail: jecfa@who.int

Three copies of the data are required, one for submission to the address above, one for submission directly to the WHO Temporary Adviser who will be reviewing the data (which should include a paper copy), and one for the Member assigned to peer review the working paper. Please contact the WHO Joint Secretary prior to submission of the data for information on where to send the copies.

***Data relevant to establishing MRLs***

Data relevant to the evaluation of residues in food products of animal origin, including:

1. Chemical identity and properties of the drug;
2. Its use and dosage range;
3. Pharmacokinetic and metabolic studies in experimental animals, target animals, and humans if available (information required by both FAO and WHO);
4. Residue-depletion studies with radiolabelled drug in target animals from zero withdrawal time to periods extending beyond the recommended withdrawal time (these studies should provide

information on total residues, including free and bound residues, and major residue components to permit selection of marker residue and target tissues);

5. Residue-depletion studies with unlabelled drug for the analysis of marker residue in target animals and in eggs, milk, and honey (these should include studies with appropriate formulations, routes of application, and species, at doses up to the maximum recommended);
6. A description of the analytical procedures used by the sponsor for the detection and determination of parent drug residues with information on validation and performance characteristics; and
7. A review of routine analytical methods that may be used by regulatory authorities for the detection of residues in target tissue, including information on quality assurance systems and sampling procedures recommended.

Three copies of the data are required, one for submission to the address below, and two for submission directly to the FAO experts who will be reviewing the data. Please contact the FAO Joint Secretary prior to submission of the data for information on where to send the copies.

Nutrition and Consumer Protection Division
Attention: Dr. Annika Wennberg
Food and Agriculture Organization of the United Nations
Via delle Terme di Caracalla
00153 Rome
Italy
Facsimile: (+39) 06 5705 4593
Telephone: (+39) 06 5705 3283
E-mail: annika.wennberg@fao.org

***Presentation of data***

Please note that the above lists are not meant to be all-inclusive since it is recognized that other studies may, in some instances, assist in the evaluation.

Procedures for the evaluation of chemicals in food were updated and recently published by FAO and WHO (Methods and *Principles for the Safety Assessment of Food Additives and Contaminants in Food* – Environmental Health Criteria No. 240, available at http://www.who.int/ipcs/food/principles/en/index1.html ).

All relevant data, both positive and negative, should be submitted. Data should be presented, summarized and referenced in a clear and concise manner, as described in the guidelines which are available at:

http://www.fao.org/ag/agn/agns/jecfa_guidelines_1_en.asp
http://www.who.int/ipcs/food/jecfa/en/guidelines_vet_drugs.pdf

Additional information on the estimation of intake and on the statistical calculations is available at the FAO JECFA website at: http://www.fao.org/ag/agn/agns/jecfa_archive_statistical_en.asp .

## Annex 1

### Joint FAO/WHO Expert Committee on Food Additives (JECFA)
### Seventy-fifth meeting, Rome, 7 – 17 November 2011

### List of substances scheduled for evaluation or re-evaluation

General information: Links to available electronic versions of the reports published in the WHO Technical Report Series, toxicological monographs published in the WHO Food Additives Series and residue monographs published in the FAO JECFA Monograph series and the FAO Food and Nutrition Paper 41 series that are referenced below are available at the JECFA web-pages of FAO and WHO. FAO and WHO procedural guidelines and guidelines for the preparation of toxicological working papers and guidelines for the preparation of working papers on the residue evaluation are available at http://www.who.int/ipcs/food/jecfa/guidelines/en/ and http://www.fao.org/ag/agn/agns/jecfa_guidelines_en.asp .

**Note: It is necessary to consult the requirements and background, including previous evaluations, as contained in previous reports and monographs of the Committee before submitting data.**

| Substance | References | Data required |
|---|---|---|
| **New Evaluations** | | |
| Amoxicillin | Paragraph 83 and Appendix VI of the report of the nineteenth Session of CCRVDF[(1)] | All data necessary to establish an ADI and recommend MRLs in cattle, sheep and pig tissues and cattle and sheep milk. |
| Apramycin | Paragraph 83 and Appendix VI of the report of the nineteenth Session of CCRVDF[(1)] | All data necessary to establish an ADI and recommend MRLs in cattle, pig, chicken and rabbit tissues. |
| Derquantel | Paragraph 83 and Appendix VI of the report of the nineteenth Session of CCRVDF[(1)] | All data necessary to establish an ADI and recommend MRLs in cattle, pigs and poultry tissues. |
| Monepantel | Paragraph 83 and Appendix VI of the report of the nineteenth Session of CCRVDF[(1)] | All data necessary to establish an ADI and recommend MRLs in sheep tissues. |

| Substance | Reference | Data required |
|---|---|---|
| **Re-evaluations** | | |
| Ivermectin | Paragraph 83 and Appendix VI of the report of the nineteenth Session of CCRVDF[1], report of the twenty-sixth Session of CAC[5], report of the twentieth Session of CAC[6], fifty-eighth report of JECFA[7], FNP 41/14[8], fifty-fourth report of JECFA[9], FNP 41/13[10], fortieth report of JECFA[11], FNP 41/5[12], thirty-sixth report of JECFA[13], FNP 41/3[14], FAS 31[15]. | All relevant data necessary for re-evaluation of the ADI and the Codex MRLs for cattle, pig and sheep tissues and cattle milk. |
| Monensin | Paragraph 83 and Appendix VI of the report of the nineteenth Session of CCRVDF[1] , seventieth report of JECFA[2], FAS 61[3], FAO JECFA Monographs 6[4]. | All relevant data necessary for re-evaluation of the Codex MRLs for cattle liver. |
| Narasin | Paragraph 83 and Appendix VI of the report of the nineteenth Session of CCRVDF[1], seventieth report of JECFA[2], FAS 61[3], FAO JECFA Monographs 6[4]. | All relevant data related to methods of analysis for the control of narasin residues in cattle tissues taking into consideration the temporary MRLs assigned. |
| Triclabendazole | Paragraph 76 and 83 and Appendix VI of the report of the nineteenth Session of CCRVDF[1], seventieth report of JECFA[2], FAO JECFA Monographs 6[4], Sixty-sixth report of JECFA[16], FAO JECFA Monographs 2[17], Fortieth report of JECFA[11] . | All relevant data and information for consideration for recommendation of MRLs in goat tissues, in particular data to consider extrapolation from MRLs recommended for cattle and sheep tissues. |

## References


1. Report of the nineteenth Session of the Codex Committee on Residues of Veterinary Drugs in Foods, Burlington, Vermont, USA, 30 August – 3 September 2010 (ALINORM REP11RVDF).
2. Evaluation of certain veterinary drug residues in food (Seventieth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 954, 2009.
3. Toxicological evaluation of certain veterinary drug residues in food. WHO Food Additives Series, No. 61, 2009.
4. Residue evaluation of certain veterinary drugs (Seventieth Joint FAO/WHO Expert Committee on Food Additives). FAO JECFA Monographs 6, 2008.
5. Report of the twenty-sixth Session of the Joint FAO/WHO Codex Alimentarius Commission, Rome, Italy, 30 June – 7 July, 2003 (ALINORM 03/41).
6. Report of the twentieth Session of the Joint FAO/WHO Codex Alimentarius Commission, Geneva, Switzerland, 28 June – 7 July, 1993 (ALINORM 93/40).
7. Evaluation of certain veterinary drug residues in food (Fifty-eight report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 911, 2002.
8. Residues of some veterinary drugs in animals and foods. FAO Food and Nutrition Paper, No. 41/14, 2002.
9. Evaluation of certain veterinary drug residues in food (Fifty-fourth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 900, 2001
10. Residues of some veterinary drugs in animals and foods. FAO Food and Nutrition Paper, No. 41/13, 2000.
11. Evaluation of certain veterinary drug residues in food (Fortieth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 832, 1993.
12. Residues of some veterinary drugs in animals and foods. FAO Food and Nutrition Paper, No. 41/5, 1992.
13. Evaluation of certain veterinary drug residues in food (Thirty-sixth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 799, 1990.
14. Residues of some veterinary drugs in animals and foods. FAO Food and Nutrition Paper, No. 41/3, 1990.
15. Toxicological evaluation of certain veterinary drug residues in food. WHO Food Additive Series, No. 31, 1993.
16. Evaluation of certain veterinary drug residues in food (Sixty-sixth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 939, 2006.
17. Residue evaluation of certain veterinary drugs. Joint FAO/WHO Expert Committee on Food Additives, 66$^{th}$ meeting. FAO JECFA Monographs 2, 2006.

## Annex 2

### JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

### BACKGROUND

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) was established in the mid-1950s by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to assess chemical additives in food on an international basis. The first meeting was held in 1956 in response to recommendations made at an FAO/WHO Conference on Food Additives that met in Geneva in 1955.

In the early 1960s the Codex Alimentarius Commission (CAC), which is an international intergovernmental body, was established. The primary aims of the CAC are to protect the health of the consumer and facilitate international trade in food. At the time that the CAC was formed it was decided that JECFA would provide expert advice to Codex on matters relating to food additives. A system was established whereby the Codex Committee on Food Additives, a general subject committee, identified food additives that should receive priority attention, which were then referred to JECFA for assessment before being considered for inclusion in Codex Food Standards.

This system is still in place, but it has been expanded to include food contaminants and residues of veterinary drugs in food to provide advice to the presently-existing Codex Committee on Food Additives (CCFA), Codex Committee on Contaminants in Food (CCCF) and Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). JECFA also provides scientific advice directly to FAO and WHO Member States, and requests for assessment may come directly from them. JECFA is not a component of the CAC.

Specialists invited to serve as Members of JECFA are independent scientists who serve in their individual capacities as experts, and not as representatives of their governments or employers. The goal is to establish safe levels of intake and to develop specifications for identity and purity (food additives) or maximum residue limits when veterinary drugs are used in accordance with good practice in the use of veterinary drugs.

Through 2010, a total of seventy-three meetings of JECFA have been held. The reports are published in the WHO Technical Report Series. The toxicological evaluations, that summarize the data that serve as the basis for the safety assessments, are published in the WHO Food Additives Series. The specifications and veterinary drug residue evaluations are published in the FAO JECFA Monographs. The Combined Compendium of Food Additive Specifications of all current JECFA specifications is available on-line http://www.fao.org/ag/agn/jecfa-additives/search.html . The newly updated data base on specifications for flavouring agents is available at http://www.fao.org/ag/agn/jecfa-flav/search.html . The monographs of the veterinary drug residue evaluations are also available in an on-line searchable database at http://www.fao.org/ag/agn/jecfa-vetdrugs/search.html .

A *Summary of Evaluations* performed by the Joint FAO/WHO Expert Committee on Food Additives, a comprehensive document that summarizes all JECFA evaluations from the first through recent meetings, is available free of charge in a searchable format at http://apps.who.int/ipsc/database/evaluations/search.aspx .